

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE LITIGATION

)
)
) MDL NO. 1456
) Civil Action No. 01-12257-PBS
)

THIS DOCUMENT RELATES TO:

) Judge Patti B. Saris
)

The City of New York v. Abbott Laboratories, Inc., et al.
(S.D.N.Y. No. 04-CV-06054)

County of Albany v. Abbott Laboratories, Inc., et al.
(N.D.N.Y. No. 05-CV-00425)

County of Allegany v. Abbott Laboratories, Inc., et al.
(W.D.N.Y. No. 05-CV-06231)

County of Broome v. Abbott Laboratories, Inc., et al.
(N.D.N.Y. No. 05-CV-00456)

County of Cattaraugus v. Abbott Laboratories, Inc., et al.
(W.D.N.Y. No. 05-CV-06242)

County of Cayuga v. Abbott Laboratories, Inc., et al.
(N.D.N.Y. No. 05-CV-00423)

County of Chautauqua v. Abbott Laboratories, Inc., et al.
(W.D.N.Y. No. 05-CV-06204)

County of Chemung v. Abbott Laboratories, Inc., et al.
(W.D.N.Y. No. 05-CV-06744)

County of Chenango v. Abbott Laboratories, Inc., et al.
(N.D.N.Y. No. 05-CV-00354)

County of Columbia v. Abbott Laboratories, Inc., et al.
(N.D.N.Y. No. 05-CV-00867)

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ANSWER AND AFFIRMATIVE DEFENSES OF
BOEHRINGER INGELHEIM ROXANE INC. TO
REVISED FIRST AMENDED CONSOLIDATED COMPLAINT

County of Cortland v. Abbott Laboratories, Inc., et al.)
(N.D.N.Y. No. 05-CV-00881))
County of Dutchess v. Abbott Laboratories, Inc., et al.)
(S.D.N.Y. No. 05-CV-06458))
County of Essex County v. Abbott Laboratories, Inc., et al.)
(N.D.N.Y. No. 05-CV-00878))
County of Fulton v. Abbott Laboratories, Inc., et al.)
(N.D.N.Y. No. 05-CV-00519))
County of Genesee v. Abbott Laboratories, Inc., et al.)
(W.D.N.Y. No. 05-CV-06206))
County of Greene v. Abbott Laboratories, Inc., et al.)
(N.D.N.Y. No. 05-CV-00474))
County of Herkimer v. Abbott Laboratories, Inc., et al.)
(N.D.N.Y. No. 05-CV-00415))
County of Jefferson v. Abbott Laboratories, Inc., et al.)
(N.D.N.Y. No. 05-CV-00715))
County of Lewis v. Abbott Laboratories, Inc., et al.)
(N.D.N.Y. No. 05-CV-00839))
County of Madison v. Abbott Laboratories, Inc., et al.)
(N.D.N.Y. No. 05-CV-00714))
County of Monroe v. Abbott Laboratories, Inc., et al.)
(W.D.N.Y. No. 05-CV-06148))
County of Nassau v. Abbott Laboratories, Inc., et al.)
(E.D.N.Y. No. 04-CV-5126))
County of Niagara v. Abbott Laboratories, Inc., et al.)
(W.D.N.Y. No. 05-CV-06296))
County of Oneida v. Abbott Laboratories, Inc., et al.)
(N.D.N.Y. No. 05-CV-00489))
County of Onondaga v. Abbott Laboratories, Inc., et al.)
(N.D.N.Y. No. 05-CV-00088))
County of Ontario v. Abbott Laboratories, Inc., et al.)
(W.D.N.Y. No. 05-CV-06373))
County of Orange v. Abbott Laboratories, Inc., et al.)
(S.D.N.Y. No. 07-CV-2777))
County of Orleans v. Abbott Laboratories, Inc., et al.)
(W.D.N.Y. No. 05-CV-06371))
County of Putnam v. Abbott Laboratories, Inc., et al.)
(S.D.N.Y. No. 05-CV-04740))

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<i>County of Rensselaer v. Abbott Laboratories, Inc., et al.</i>)
(N.D.N.Y. No. 05-CV-00422))
<i>County of Rockland v. Abbott Laboratories, Inc., et al.</i>)
(S.D.N.Y. No. 03-CV-7055))
<i>County of Saratoga v. Abbott Laboratories, Inc., et al.</i>)
(N.D.N.Y. No. 05-CV-00478))
<i>County of Schuyler v. Abbott Laboratories, Inc., et al.</i>)
(W.D.N.Y. No. 05-CV-06387))
<i>County of Seneca v. Abbott Laboratories, Inc., et al.</i>)
(W.D.N.Y. No. 05-CV-06370))
<i>County of St. Lawrence v. Abbott Laboratories, Inc., et al.</i>)
(N.D.N.Y. No. 05-CV-00479))
<i>County of Steuben v. Abbott Laboratories, Inc., et al.</i>)
(W.D.N.Y. No. 05-CV-06223))
<i>County of Suffolk v. Abbott Laboratories, Inc., et al.</i>)
(E.D.N.Y. No. CV-03-229))
<i>County of Tompkins v. Abbott Laboratories, Inc., et al.</i>)
(N.D.N.Y. No. 05-CV-00397))
<i>County of Ulster v. Abbott Laboratories, Inc., et al.</i>)
(N.D.N.Y. No. 06-CV-0123))
<i>County of Warren v. Abbott Laboratories, Inc., et al.</i>)
(N.D.N.Y. No. 05-CV-00468))
<i>County of Washington v. Abbott Laboratories, Inc., et al.</i>)
(N.D.N.Y. No. 05-CV-00408))
<i>County of Wayne v. Abbott Laboratories, Inc., et al.</i>)
(W.D.N.Y. No. 05-CV-06138))
<i>County of Westchester v. Abbott Laboratories, Inc., et al.</i>)
(S.D.N.Y. No. 03-CV-6178))
<i>County of Wyoming v. Abbott Laboratories, Inc., et al.</i>)
(W.D.N.Y. No. 03-CV-6379))
AND)
<i>County of Yates v. Abbott Laboratories, Inc., et al.</i>)
(W.D.N.Y. No. 05-CV-06172))

Defendant Boehringer Ingelheim Roxane, Inc., f/k/a Roxane Laboratories, Inc. (“Roxane”) hereby states as its Answer and Affirmative Defenses to the Revised First Amended Consolidated Complaint, filed on October 5, 2007, as follows:

PRELIMINARY STATEMENT

The Revised First Amended Consolidated Complaint (the “Complaint”) improperly refers to Roxane, other defendants, and third parties on a collective basis, failing to plead with requisite particularity allegations against Roxane. This is insufficient to apprise Roxane (let alone each separate entity) of the allegations asserted against it. Roxane has nevertheless attempted to respond to Plaintiffs’ allegations to the extent possible.

To the extent the allegations in the Complaint refer to the knowledge, conduct or actions of other persons or entities, Roxane generally lacks knowledge or information sufficient to form a belief as to the truth of those allegations. Roxane states that it is answering Plaintiffs’ allegations solely on behalf of itself, even when Plaintiffs’ allegations refer to alleged conduct by Roxane and other persons or entities.

The Complaint also contains purported quotations from a number of sources. In answering allegations consisting of quotations, Roxane’s failure to deny that the material quoted was contained in a document or was uttered by the person or entity quoted or Roxane’s reference to the full document instead of the quote shall not constitute an admission that the substantive content of the quote or document is or is not true or that the material is relevant or admissible in this action.

Roxane denies each and every allegation contained in the Complaint and the exhibits thereto, except as specifically herein admitted, and any factual averment admitted herein is admitted only as to the specific facts and not as to any conclusions, characterizations,

implications, innuendos or speculation contained in any particular averment or in the Complaint as a whole. In addition, Roxane specifically denies any allegations contained in headings, footnotes, or unnumbered paragraphs in the Complaint. For ease of reference, Roxane has included in this Answer and Affirmative Defenses the caption used in the Complaint, but specifically denies any allegations contained in, or inferences that could be drawn from, that caption.

These comments and objections are incorporated, to the extent appropriate, into each unnumbered and numbered paragraph of this Answer.

SPECIFIC RESPONSES

To the extent that the unnumbered paragraph immediately following the Table of Contents (the “Complaint’s Introductory Paragraph”) makes allegations against Roxane, Roxane denies them, except admits that the City of New York and certain New York Counties (collectively, the “Counties”) have made allegations against a number of defendants, including Roxane, as set forth in the Complaint. To the extent that the Complaint’s Introductory Paragraph states legal conclusions, no response is required. To the extent the allegations of the Complaint’s Introductory Paragraph are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

1. Roxane admits that the Counties seek to bring this action as alleged in Paragraph 1 of the Complaint, but Roxane denies there is any basis for them to do so and denies that they are entitled to any relief. Roxane also admits that Exhibits B1-B-40 to the Complaint purport to identify the prescription drugs at issue in this matter, but denies any liability to Plaintiffs with respect to any such NDCs. To the extent the remaining allegations in Paragraph 1 are directed at Roxane, Roxane denies them. Roxane specifically denies that it has been involved in “fraudulent

and misleading schemes” or that the New York State Medicaid Program has been “overcharge[d]” for prescription drugs. To the extent the remaining allegations in Paragraph 1 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

2. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 or the exhibit referenced therein, and therefore denies them. To the extent the allegations in Paragraph 2 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

3. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 or its footnote and therefore denies them, except admits that it pays Medicaid rebates to the State of New York and that such rebates lower the price New York Medicaid pays for Roxane’s prescription drugs. To the extent the allegations in Paragraph 3 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

4. To the extent the allegations in Paragraph 4 are directed at Roxane, Roxane denies them. Roxane specifically denies that it was involved in “fraudulent schemes,” the “manipulation of the Medicaid program” or the “intentional fraudulent inflation” of wholesale prices, or that the Counties’ Medicaid Programs were “overcharge[d].” To the extent the allegations in Paragraph 4 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

5. To the extent the allegations in Paragraph 5 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Roxane otherwise

lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5, and therefore denies these allegations.

6. To the extent the allegations in Paragraph 6 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Roxane otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 6 or its footnote and therefore denies them, and Roxane denies that it “actively encourage[s] physicians to write DAW in order to secure AWP-based reimbursement for pharmacies.”

7. To the extent the allegations in Paragraph 7 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Roxane otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 7, and therefore denies these allegations.

8. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 8, and therefore denies these allegations.

9. To the extent the allegations in Paragraph 9 are directed at Roxane, Roxane denies them. Roxane specifically denies that it “control[s] and unlawfully inflates[s]” average wholesale prices (“AWPs”) or federal upper limits (“FULs”). To the extent the allegations in Paragraph 9 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

10. To the extent the allegations in Paragraph 10 are directed at Roxane, Roxane denies them, except Roxane admits that it has provided the wholesale list price of its drugs to certain industry pricing compendia and that publishers apply their own markups to the list prices.

Roxane specifically denies that it “set[s] AWP.” To the extent the allegations in Paragraph 10 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

11. To the extent the allegations in Paragraph 11 are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraph 11 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

12. To the extent the allegations in Paragraph 12 or the exhibit referenced therein are directed at Roxane, Roxane denies them. Roxane specifically denies that it has “report[ed] a false and inflated WAC or WAC equivalent” to industry pricing compendia. To the extent the allegations in Paragraph 12 or the exhibit referenced therein are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

13. To the extent the allegations in Paragraph 13 are directed at Roxane, Roxane denies them, except Roxane admits that CMS has established FULs for certain drugs. Roxane specifically denies that it “control[s] the FUL.” To the extent the allegations in Paragraph 13 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraph 13 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

14. To the extent the allegations in Paragraph 14 are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraph 14 are directed at parties other than

Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

15. To the extent the allegations in Paragraph 15 or the exhibit referenced therein are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraph 15 or the exhibit referenced therein are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

16-17. To the extent the allegations in Paragraphs 16-17 are directed at Roxane, Roxane denies them. Roxane specifically denies that it “submit[s] false and inflated price information to the publishing compendia.” Roxane further denies the characterization of “spread” in Paragraphs 16-17. To the extent the allegations in Paragraphs 16-17 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

18-19. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 18-19, and therefore denies these allegations.

20. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 20. To the extent the allegations in Paragraph 20 refer to a Wall Street Journal article, the article speaks for itself, and any characterizations thereof are denied.

21. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 21 or the exhibit referenced therein, and therefore denies these allegations.

22. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 22, and therefore denies these allegations.

23. To the extent the allegations in Paragraph 23 are directed at Roxane, Roxane denies them. Roxane specifically denies that it has “secretly polluted the entire reimbursement system with false and inflated prices.” To the extent the allegations in Paragraph 23 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

24. To the extent the allegations in Paragraph 24 or the exhibit referenced therein are directed at Roxane, Roxane denies them. Roxane specifically denies that it has “cause[d] false and inflated published reimbursement prices to issue.” Roxane further denies the characterization of “spread” in Paragraph 24. To the extent the allegations in Paragraph 24 or the exhibit referenced therein are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

25. To the extent the allegations in Paragraph 25 are directed at Roxane, Roxane denies them. Roxane specifically denies that it has “create[d], inflate[d], manipulate[d] and market[ed] the spread for both brand name and generic drugs.” To the extent the allegations in Paragraph 25 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

26. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 26, and therefore denies these allegations. To the extent the allegations in Paragraph 26 refer to a HHS OIG report, the report speaks for itself, and any characterizations thereof are denied.

27. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 27, and therefore denies these allegations. To the extent the

allegations in Paragraph 27 refer to the transcript of a congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.

28. To the extent the allegations in Paragraph 28 or the exhibit referenced therein are directed at Roxane, Roxane denies them. Roxane specifically denies that it has engaged in “intentional AWP inflation” or “fraud.” Roxane further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the Counties and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices or have an expected relationship to such an average. To the extent the allegations in Paragraph 28 or the exhibit referenced therein are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

29. To the extent the allegations in Paragraph 29 are directed at Roxane, Roxane denies them. Roxane specifically denies that it has “reported or caused to be reported [] false and inflated” WACs or engaged in any “unlawful and undisclosed manipulation of the price reporting system.” To the extent the allegations in Paragraph 29 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

30. To the extent the allegations in Paragraph 30 or the exhibit referenced therein are directed at Roxane, Roxane denies them. Roxane specifically denies that it has engaged in any “pricing misconduct.” To the extent the allegations in Paragraph 30 or the exhibit referenced therein are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

31. To the extent the allegations in Paragraph 31 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Roxane otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 31 or its footnote and therefore denies them, except Roxane admits that it pays Medicaid rebates as required by law.

32. To the extent the allegations in Paragraph 32 are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraph 32 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth.

33. To the extent the allegations in Paragraph 33 or its footnote are directed at Roxane, Roxane denies them. Roxane specifically denies that it has “abused” any Medicaid statute. To the extent the allegations in Paragraph 33 or its footnote are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations. To the extent the allegations in Paragraph 33 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

34. To the extent the allegations in Paragraph 34 are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraph 34 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations. To the extent the allegations in Paragraph 34 refer to a HHS OIG report, the report speaks for itself, and any characterizations thereof are denied.

35. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 35, and therefore denies these allegations.

36. To the extent the allegations in Paragraph 36 or the exhibit referenced therein are directed at Roxane, Roxane denies them, except Roxane admits that some states have investigated drug pricing issues and have filed lawsuits against Roxane and other defendants. To the extent the allegations in Paragraph 36 or the exhibit referenced therein are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

37. Roxane admits that the Counties seeks the relief listed in Paragraph 37, but Roxane denies there is any basis for them to do so and denies that they are entitled to any relief. To the extent the remaining allegations in Paragraph 37 are directed at Roxane, Roxane denies them. Roxane specifically denies that it has been involved in any “fraudulent and illegal manipulation of drug prices.” To the extent the remaining allegations in Paragraph 37 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

38. Roxane admits that the Counties seek to bring this action as alleged in Paragraph 38, but Roxane denies there is any basis for them to do so and denies that they are entitled to any relief.

39-40. Paragraphs 39-40 state legal conclusions as to which no response is required. To the extent a response is deemed to be required, Roxane denies the allegations in Paragraphs 39-40, except admits that each of the captioned matters has been transferred to this Court by the Judicial Panel on Multi District Litigation pursuant to 28 U.S.C. 1407.

41-42. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 41-42, and therefore denies these allegations. To the extent the

allegations in Paragraphs 41-42 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

42A. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 42A. To the extent the allegations in Paragraph 42A refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

43. Roxane denies the allegations in Paragraph 43 and its footnote, and refers to Case Management Order No. 33, dated September 14, 2007, ¶¶ 1, 3 for which plaintiffs are suing which defendants.

44. To the extent the allegations in Paragraph 44 are directed at Roxane, Roxane denies them, except Roxane admits that it manufactures prescription drugs. Roxane denies, for the time period April, 2005 to the present, that Roxane has engaged in the business of selling prescription drugs. Roxane admits that defendant Ben Venue Laboratories, Inc. ("Ben Venue") manufactures and sells prescription drugs. Roxane further admits that Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") manufactures and sells prescription drugs. Roxane denies that Boehringer Ingelheim Corporation ("Boehringer") manufactures or sells prescription drugs. Roxane specifically denies that Roxane, Ben Venue, BIPI or Boehringer "manufactures, markets and sells prescription drugs with false and inflated wholesale prices." Roxane lacks knowledge or information sufficient to form a belief as to the truth about which prescription drugs "are paid for by the County Medicaid Programs," and therefore denies this allegation. Roxane admits that BIPI, Ben Venue and Roxane transact business within the State of New York, including within the City of New York and in the Counties. Roxane denies any remaining allegations of Paragraph 44 directed at Roxane. To the extent the allegations in Paragraph 44 are directed at

parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

45-53. The allegations in Paragraphs 45-53 are directed to other defendants and require no response from Roxane. To the extent a response is deemed to be required, Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 45-53, and therefore denies these allegations.

54. With respect to the allegations in Paragraph 54 and the sub-parts thereof, Roxane admits that Boehringer is a Nevada corporation with its principal place of business located at 900 Ridgebury Rd., Ridgefield, CT 06877, that Boehringer is a subsidiary of Pharma Investment Limited of Burlington, Canada ("Pharma") and that C.H. Boehringer Sonn Grundstücksverwaltung GmbH & Co. KG ("C.H. Boehringer") is a German corporation located in Ingelheim, Germany. Roxane denies the remaining allegations that pertain to Pharma and C.H. Boehringer. Roxane admits that Roxane is a Delaware corporation engaged in the business of manufacturing pharmaceuticals, with its principal place of business located at 1809 Wilson Road, Columbus, OH 43216-6532. Roxane admits that it is a wholly-owned subsidiary of Boehringer. Roxane denies, for the time period April, 2005 to the present, that Roxane is engaged in the business of selling pharmaceuticals. Roxane further admits that BIPI is a wholly-owned subsidiary of Boehringer, and that it is engaged in the business of manufacturing and selling pharmaceuticals. Roxane admits that BIPI's principle place of business is located at 900 Ridgebury Rd., Ridgefield, CT 06877, but denies that BIPI is a Connecticut corporation. Roxane admits that Ben Venue is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals, with its principal place of business located at 300 Northfield Road, Bedford, OH 44146. Roxane admits that Ben Venue was founded in 1938 and that Ben Venue

was acquired by Boehringer in 1997. Roxane further admits that Bedford Laboratories (“Bedford”) is a division of Ben Venue that was created in or about 1993. Roxane admits that Roxane, BIPI, and Ben Venue are subsidiaries of Boehringer. Roxane affirmatively avers that reference to Roxane, BIPI and Ben Venue, three separate corporate entities, as the “Boehringer Group” is inappropriate and improper. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 54 and its sub-parts, and therefore denies these allegations.

55-84. The allegations in Paragraphs 55-84 are directed to other defendants and require no response from Roxane. To the extent a response is deemed to be required, Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 55-84, and therefore denies these allegations.

85-88. The allegations in Paragraphs 85-88 are directed to unknown defendants and require no response from Roxane. To the extent a response is deemed to be required, Roxane denies that it was involved in any conspiracy related to drug pricing with either named or unknown defendants. Roxane also denies that it has engaged in any “wrongful acts” related to drug pricing.

89. With respect to the allegations in Paragraph 89, Roxane admits that Medicaid was established by Title XIX of the Social Security Act. Roxane further states that the provisions of Title XIX speak for themselves, and any characterizations thereof are denied.

90. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 90, and therefore denies them, except Roxane admits that state participation in Medicaid is voluntary and that state Medicaid plans must be approved by the

federal government. To the extent the allegations in Paragraph 90 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

91-99. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 91-99 or their footnotes, and therefore denies them. To the extent the allegations in Paragraphs 91-99 or their footnotes refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

100. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 100, and therefore denies them, except admits that national drug codes are assigned to prescription drugs and that the FDA assigns such codes.

101-111. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 101-111 or their footnotes, and therefore denies these allegations. To the extent the allegations in Paragraphs 101-111 or their footnotes refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

112. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 112, and therefore denies them, except admits that pricing compendia, such as Blue Book, publish AWP's and FULs, and denies that Roxane has any control over such prices.

113. To the extent the allegations in Paragraph 113 are directed at Roxane, Roxane denies them. Roxane specifically denies that it has "fraudulently conceal[ed]" the "true prices" of its drugs by "claiming they are proprietary trade secrets." To the extent the allegations in Paragraph 113 are directed at parties other than Roxane, Roxane lacks knowledge or information

sufficient to form a belief as to their truth, and therefore denies these allegations. To the extent the allegations in Paragraph 113 refer to the transcript of a congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.

114-115. To the extent the allegations in Paragraphs 114-115 are directed at Roxane, Roxane denies them. Roxane specifically denies that it reports “reimbursement prices . . . to the publishing compendia” or that it has engaged in the “purposeful manipulation of reimbursement prices generally, and AWP in particular.” Roxane further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the Counties and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 114-115 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations. To the extent the allegations in Paragraphs 114-115 refer to HHS OIG reports, the reports speak for themselves, and any characterizations thereof are denied.

116-123. With respect to the allegations in Paragraphs 116-123 and their footnotes, Roxane admits that the Medicaid statute includes a rebate provision, that it has entered into a rebate agreement with the Secretary of Health and Human Services, and that rebates help reduce state Medicaid drug expenditures. Roxane further states that the rebate provision speaks for itself, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 116-123 or their footnotes refer to additional statutes, regulations or congressional reports, those sources also speak for themselves, and any characterizations thereof are also denied.

124-125. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 124-125, and therefore denies these allegations. To the

extent the allegations in Paragraphs 124-125 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Roxane denies that the Counties are intended third-party beneficiaries of Medicaid rebate agreements.

126. With respect to the allegations in Paragraph 126, Roxane admits that drug manufacturers report Best Prices and AMPs to HHS. To the extent the allegations in Paragraph 126 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

127-130. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 127-130, and therefore denies them, except admits that it reports Medicaid information to HHS and pays rebates to States. To the extent the allegations in Paragraphs 127-130 refer to statutes, regulations or amicus briefs filed by the United States, those sources speak for themselves, and any characterizations thereof are denied.

131. To the extent the allegations in Paragraph 131 are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraph 131 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations. To the extent the allegations in Paragraph 131 refer to the Model Rebate Agreement, that document speaks for itself, and any characterizations thereof are denied.

132. To the extent the allegations in Paragraph 132 are directed at Roxane, Roxane admits that it has executed a rebate agreement with HHS. Roxane further states that the rebate agreement speaks for itself, and any characterizations thereof are denied. To the extent the allegations in Paragraph 132 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

To the extent the allegations in Paragraph 132 refer to the Model Rebate Agreement, that document also speaks for itself, and any characterizations thereof are also denied.

133-136. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 133-136. To the extent the allegations in Paragraphs 133-136 refer to the Model Rebate Agreement, that document speaks for itself, and any characterizations thereof are denied.

137-143. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 137-143, and therefore denies them, and Roxane denies that the Counties are Medicaid payors or intended third-party beneficiaries of Medicaid rebate agreements. To the extent the allegations in Paragraphs 137-143 refer to statutes, regulations or amicus briefs filed by the United States, those sources speak for themselves, and any characterizations thereof are denied.

144. To the extent the allegations in Paragraph 144 are directed at Roxane, Roxane denies them. Roxane specifically denies that it “intentionally reported, or caused to be reported, to industry publications wholesale pricing information that it knew to be false and inflated.” Roxane further denies the characterization of “spread” in Paragraph 144. To the extent the allegations in Paragraph 144 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

145-149. With respect to the allegations in Paragraphs 145-149, Roxane admits that Exhibit B to the Complaint purports to identify the prescription drugs at issue in this matter, but denies the accuracy of the data listed therein. To the extent the remaining allegations in Paragraphs 145-149 or Exhibit B are directed at Roxane, Roxane denies them. Roxane specifically denies that it “routinely submitted fraudulent prices” to pricing compendia. Roxane

further denies the characterization of “spread” in Paragraphs 145-149 and Exhibit B. To the extent the remaining allegations in Paragraphs 145-149 or Exhibit B are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

150-153. To the extent the allegations in Paragraphs 150-153 are directed at Roxane, Roxane denies them. Roxane further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the Counties and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 150-153 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

154. Paragraph 154 purports to contain a statement from HHS OIG, but Roxane lacks knowledge or information sufficient to form a belief as to its accuracy because the source thereof is not provided, and therefore denies these allegations. To the extent the source of the statement is provided, the source speaks for itself, and any characterizations thereof are denied.

155. To the extent the allegations in Paragraph 155 are directed to Roxane, Roxane denies them. Roxane further states that these allegations wrongly assume that discounts, chargebacks and other price concessions are supposed to be included in prices reported to industry compendia. To the extent the allegations in Paragraph 155 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies them.

156. Roxane admits that it pays “chargebacks” but denies the remaining allegations in Paragraph 156. To the extent the allegations in Paragraph 156 are directed at parties other than

Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies them.

157. Roxane admits that it pays prompt pay discounts when it is paid within the prescribed period of time, but denies the remaining allegations in Paragraph 157. Roxane further states that these allegations wrongly assume that discounts, chargebacks and other price concessions are supposed to be included in prices reported to industry compendia. To the extent the allegations in Paragraph 157 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies them.

158. To the extent the allegations in Paragraph 158 are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraph 158 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies them.

159-165. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 159-165, and therefore denies them, except Roxane admits that PBMs are involved in administering and managing prescription drug benefit programs and that certain PBMs also operate mail order pharmacies. To the extent the allegations in Paragraphs 159-165 refer to articles or reports, those sources speak for themselves, and any characterizations thereof are denied.

166. To the extent the allegations in Paragraph 166 are directed at Roxane, Roxane denies them. Roxane specifically denies that it “control[s] the published reimbursement prices.” To the extent the allegations in Paragraph 166 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

167. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 167, and therefore denies these allegations.

168-172. To the extent the allegations in Paragraphs 168-172 are directed at Roxane, Roxane denies them, except Roxane admits that it has executed a rebate agreement with HHS. Roxane further states that the Court has dismissed all Medicaid rebate-related allegations in the Complaint as to Roxane. In any event, the rebate agreement speaks for itself, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 168-172 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations. To the extent the allegations in Paragraphs 168-172 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

173-176. To the extent the allegations in Paragraphs 173-176 are directed at Roxane, Roxane denies them, and further states that the Court has dismissed all Medicaid rebate-related allegations in the Complaint as to Roxane. To the extent the allegations in Paragraphs 173-176 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations. To the extent the allegations in Paragraphs 173-176 refer to statutes, regulations or reports, those sources speak for themselves, and any characterizations thereof are denied.

177. To the extent the allegations in Paragraph 177 are directed at Roxane, Roxane denies them, except admits that Roxane has been asked to supply information to the House Committee on Energy and Commerce. To the extent the allegations in Paragraph 177 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

178-194. To the extent the allegations in Paragraphs 178-194 or their footnotes are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraphs 178-194 or their footnotes are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations, but Roxane admits it has been asked to supply information to the House Committee on Energy and Commerce. Roxane also admits that BIPI has been asked to supply information to the Senate Finance Committee regarding certain pricing issues. To the extent the allegations in Paragraphs 178-194 or their footnotes refer to reports, articles, letters, congressional hearing transcripts, or other documents, those sources speak for themselves, and any characterizations thereof are denied.

195. To the extent the allegations in Paragraph 195 are directed at Roxane, Roxane denies them, except Roxane admits that its contracts with purchasers sometimes included discounts. To the extent the allegations in Paragraph 195 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

196. To the extent the allegations in Paragraph 196 or the exhibit referenced therein are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraph 196 or the exhibit referenced therein are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies them.

197-341. The allegations in Paragraphs 197-341 are directed to other defendants and require no response from Roxane. To the extent a response is deemed to be required, Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 197-341, and therefore denies these allegations.

342. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 342 or its footnote or the exhibit referenced therein, and therefore denies them, and Roxane denies that it engaged in any “fraud,” and states that Exhibits A and B to the Complaint have changed since the filing of the Complaint.

343. Roxane denies the allegations in Paragraph 343 and the exhibit referenced therein.

344. Roxane admits that it prepared a “worksheet” for internal purposes that illustrated spreads between AWP and acquisition cost. Roxane denies the remaining allegations in Paragraph 344.

345. Roxane admits it has offered its prescription drugs to its customers at prices below the published AWP and that it knew some customers cared about “spread.” Roxane denies that it “actively marketed and manipulated the spread” and denies the remaining allegations in Paragraph 345. Roxane further states that for years, and at all times relevant to the Revised First Amended Consolidated Complaint, it has been common knowledge and universally understood, including by the Counties and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices.

346. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 346, and therefore denies these allegations and the exhibit referenced therein. Roxane further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the Counties and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 346 refer to published reports by HHS and DOJ, the reports speak for themselves, and any characterizations thereof are denied.

347. Roxane denies the allegations in Paragraph 347.

348. Roxane admits that it has been investigated by DOJ and that it was asked to provide information to the House Committee on Energy and Commerce. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 348, and therefore denies these allegations. Roxane specifically denies that it engaged in any “wrongful conduct.”

349. Roxane denies the allegations in Paragraph 349, except admits that it has been sued along with other defendants by the States of Alabama, Illinois, Kentucky, Ohio, Pennsylvania and Wisconsin. Roxane specifically denies that it engaged in any “wrongful conduct.”

350. Roxane admits that Ohio alleges that in 1999, Roxane and its affiliates published an AWP for ipratropium bromide of \$44.06. Roxane denies the remaining allegations in Paragraph 350 and further denies the truth of and characterizations in Ohio’s allegations.

351. Roxane denies the allegations in Paragraph 351.

352. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 352, and therefore denies these allegations. Roxane further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the Counties and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices.

353. Roxane admits that Illinois alleges that in 2000, Roxane and its affiliates published an AWP for subject drug Furosemide 20 mg tablets of \$36.05. Roxane denies the

remaining allegations in Paragraph 353 and further denies the truth of and characterizations in Illinois' allegations.

354. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 354, and therefore denies these allegations. Roxane further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the Counties and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices.

355-356. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 355-356 and therefore denies these allegations and the exhibit referenced therein. Roxane specifically denies that these prices were "false and inflated" or that these prices were "fraudulent".

357. Roxane admits that Illinois alleges that in 2000, Ben Venue and its affiliates published an AWP for subject drug Haloperidol Decanoate 100 mg/ml of \$576.00. Roxane denies the remaining allegations in Paragraph 357 and further denies the truth of and characterizations in Illinois' allegations.

358. Roxane admits that Wisconsin alleges that in 2000, Roxane and its affiliates published an AWP for subject drug Prednisone 20 mg tablets of \$57.72. Roxane denies the remaining allegations in Paragraph 358 and further denies the truth of and characterizations in Wisconsin's allegations.

359. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 359, and therefore denies these allegations.

360. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 360, and therefore denies these allegations and the exhibit referenced therein. Roxane specifically denies that these prices were “fraudulent”.

361. Roxane admits that it has been asked to supply information to the House Committee on Energy and Commerce regarding its pricing. Roxane denies the remaining allegations in Paragraph 361.

362. Roxane admits that it was sued by the state of Massachusetts, but denies the remaining allegations in Paragraph 362.

363. Roxane denies that the Massachusetts Attorney General issued a subpoena to Roxane. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 363, and therefore denies these allegations.

364. Roxane admits the Massachusetts Attorney General sued Roxane, but denies the remaining allegations in Paragraph 364.

365. Roxane denies the allegations in Paragraph 365. Roxane specifically denies that AWP and/or AMP prices were “false” or “fraudulent”. Roxane further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the Counties and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices.

366. Roxane denies the allegations in Paragraph 366 as they pertain to Roxane, but admits that BIPI has been asked to supply information to the Senate Finance Committee. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 366, and therefore denies these allegations.

367-769. The allegations in Paragraphs 367-769 are directed to other defendants and require no response from Roxane. To the extent a response is deemed to be required, Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 386-769.

770-772. To the extent the allegations in Paragraphs 770-772 are directed at Roxane, Roxane denies them, and Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegation that the Counties' Medicaid programs "spent over \$20 billion for defendants' drugs from 1992 – 2005", and therefore denies this allegation. Roxane specifically denies that it was involved in any "false price reporting scheme" or "misconduct," or that it has been "unjustly enriched." To the extent the allegations in Paragraphs 770-772 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

773-790. To the extent the allegations in Paragraphs 773-790 are directed at Roxane, Roxane denies them. Roxane further states that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the Counties and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 773-790 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations. To the extent the allegations in Paragraph 786 refer to *The Pink Sheet*, that document speaks for itself, and any characterizations thereof are denied.

COUNT I

VIOLATION OF FEDERAL MEDICAID STATUTE, 42 U.S.C. 1396r-8 (FAILURE TO COMPLY WITH FEDERAL MEDICAID REBATE PROVISION)

791. In response to Paragraph 791, Roxane repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 790.

792-800. To the extent the allegations in Paragraphs 792-800 are directed at Roxane, Roxane states that the Court has dismissed these allegations. To the extent that a response is still required, Roxane denies the allegations as to itself. To the extent the allegations in Paragraphs 792-800 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

COUNT II

VIOLATION OF N.Y. SOCIAL SERVICES LAW 367-a(7)(d) (FAILURE TO COMPLY WITH STATE MEDICAID REBATE PROVISION)

801. In response to Paragraph 801, Roxane repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 800.

802-807. To the extent the allegations in Paragraphs 802-807 are directed at Roxane, Roxane states that the Court has dismissed these allegations. To the extent that a response is still required, Roxane denies the allegations as to itself. To the extent the allegations in Paragraphs 802-807 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

COUNT III

VIOLATION OF NEW YORK SOCIAL SERVICES LAW 145-b (OBTAINING PUBLIC FUNDS BY FALSE STATEMENTS)

808. In response to Paragraph 808, Roxane repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 807.

809. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 809, and therefore denies these allegations. To the extent the allegations in Paragraph 809 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

810-813. To the extent the allegations in Paragraphs 810-813 are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraphs 810-813 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations. To the extent the allegations in Paragraphs 810-813 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 810-813 contain legal conclusions, no response is required.

COUNT IV

VIOLATION OF NEW DEPARTMENT OF HEALTH REGULATIONS 18 N.Y.C.R.R. 512.2(b)(4) and (5)

814. In response to Paragraph 814, Roxane repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 813.

815-817. To the extent the allegations in Paragraphs 815-817 are directed at Roxane, Roxane states that the Court has dismissed these allegations. To the extent that a response is still required, Roxane denies the allegations as to itself. To the extent the allegations in Paragraphs 814-817 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth.

COUNT V

BREACH OF CONTRACT

818. In response to Paragraph 818, Roxane repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 817.

819-830. To the extent the allegations in Paragraphs 819-830 are directed at Roxane, Roxane states that the Court has dismissed these allegations. To the extent that a response is still required, Roxane denies the allegations as to itself. To the extent the allegations in Paragraphs 819-830 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations.

COUNT VI

UNFAIR TRADE PRACTICES (Violations of N.Y. Gen. Bus. Law 349 *et seq.*)

831. In response to Paragraph 831, Roxane repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 830.

832-835. To the extent the allegations in Paragraphs 832-835 and the exhibits referenced therein are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraphs 832-835 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations. To the extent the allegations in Paragraphs 832-835 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

836-837. To the extent the allegations in Paragraphs 836-837 are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraphs 836-837 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations. To the extent the allegations in Paragraphs

836-837 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

838-839. To the extent the allegations in Paragraphs 838-839 and the sub-parts thereto are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraphs 838-839 and the sub-parts thereto are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations. To the extent the allegations in Paragraphs 838-839 and the sub-parts thereto refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 838-839 and the sub-parts thereto contain legal conclusions, no response is required.

COUNT VII

FRAUD

840. In response to Paragraph 840, Roxane repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 839.

841-843. To the extent the allegations in Paragraphs 841-843 and the exhibits referenced therein are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraphs 841-843 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies them.

844. Roxane lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 844 and therefore denies these allegations. To the extent the allegations in Paragraph 844 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

845. To the extent the allegations in Paragraph 845 are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraph 845 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations. To the extent the allegations in Paragraph 845 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraph 845 contain legal conclusions, no response is required.

COUNT VIII
UNJUST ENRICHMENT

846. In response to Paragraph 846, Roxane repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 845.

847-849. To the extent the allegations in Paragraphs 847-849 are directed at Roxane, Roxane denies them. To the extent the allegations in Paragraphs 847-849 are directed at parties other than Roxane, Roxane lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies these allegations. To the extent the allegations in Paragraphs 847-849 contain legal conclusions, no response is required.

850-858. Roxane denies that the Counties are entitled to a judgment or any other relief as requested in the unnumbered "WHEREFORE" Paragraph and Paragraphs 850-858 of the Complaint.

WHEREFORE, Roxane demands judgment dismissing the Complaint with prejudice, and awarding reasonable expenses and costs incurred herein, and for such further relief as the Court deems just and proper.

AFFIRMATIVE DEFENSES

Roxane reasserts and incorporates herein by reference its assertions in its Answer to Paragraphs 1 through 858 hereof.

First Affirmative Defense

Plaintiffs fail to state a claim against Roxane upon which relief may be granted.

Second Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, because they did not rely on any alleged misrepresentations or fraud by Roxane. Plaintiffs knew that providers could obtain Roxane drugs at prices below AWP prior to the relevant time period stated in the Complaint.

Third Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, by the political question and separation of powers doctrines.

Fourth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, by the filed rate doctrine.

Fifth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, by the state action doctrine.

Sixth Affirmative Defense

To the extent Plaintiffs or the State of New York obtain recovery in any other case predicated on the same factual allegations, Plaintiffs are barred from seeking recovery against Roxane based on the Complaint pursuant to the doctrines of *res judicata* and collateral estoppel, and the prohibition on double recovery for the same injury.

Seventh Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or conduct by Roxane in judicial, legislative, or administrative proceedings of any kind or at any level of government.

Eighth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, to the extent that Plaintiffs have released, settled, entered into an accord and satisfaction or otherwise compromised Plaintiffs' claims.

Ninth Affirmative Defense

Plaintiffs' state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

Tenth Affirmative Defense

Plaintiffs' claims against Roxane are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel, and waiver.

Eleventh Affirmative Defense

Plaintiffs fail to state with particularity facts to support claims of fraudulent conduct, fraudulent concealment and the multi-source allegations against Roxane contained in the Complaint.

Twelfth Affirmative Defense

Any and all actions taken by Roxane with respect to any of the matters alleged in the

Complaint were taken in good faith and in accordance with established industry practice.

Thirteenth Affirmative Defense

Roxane's statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by Plaintiffs.

Fourteenth Affirmative Defense

Roxane denies that Plaintiffs have valid consumer protection claims against Roxane under New York's Unfair Trade Practices Act. However, if such claims are found to exist, Roxane pleads all available defenses under the Act.

Fifteenth Affirmative Defense

To the extent that Plaintiffs attempt to seek equitable relief against Roxane, Plaintiffs are not entitled to such relief because Plaintiffs have an adequate remedy at law.

Sixteenth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint.

Seventeenth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, by the doctrine of consent and/or ratification to the extent that Plaintiffs have received and paid for medicines manufactured, marketed and sold by Roxane after the filing of the complaint of Suffolk County.

Eighteenth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, because the damages alleged are speculative and remote and because of the impossibility of ascertaining and allocating those alleged damages.

Nineteenth Affirmative Defense

Plaintiffs' claims against Roxane are barred, in whole or in part, due to their failure to join indispensable parties.

Twentieth Affirmative Defense

Plaintiffs' claims against Roxane are barred, in whole or in part, because Plaintiffs have not suffered damages as a result of the matters alleged in the Complaint.

Twenty-First Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs failed to mitigate damages, and that failure to mitigate damages should proportionately reduce Plaintiffs' recovery and the allocation of any fault, if any exists, attributable to Roxane.

Twenty-Second Affirmative Defense

Roxane is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiffs, with respect to the same alleged injuries.

Twenty-Third Affirmative Defense

To the extent punitive damages are sought, Plaintiffs' punitive damages claims against Roxane are not recoverable because the allegations of the Complaint are legally insufficient to support a claim for punitive damages against Roxane.

Twenty-Fourth Affirmative Defense

To the extent punitive damages are sought, Plaintiffs' damages claims against Roxane cannot be sustained because an award of punitive damages would violate the United States Constitution, Excessive Fines Clause of the Eighth Amendment, U.S. Const. amend. VIII and the Due Process Clause of the Fourteenth Amendment, U.S. Const. amend. XIV, § 1 and the

analogous provisions contained in the Constitutions of the State of New York and any other States whose laws are or become relevant in the course of this lawsuit.

Twenty-Fifth Affirmative Defense

Roxane adopts by reference any additional applicable defense pled by any other defendant not otherwise pled herein.

Twenty-Sixth Affirmative Defense

Roxane hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserve its right to amend its Answer to assert such defense.

Date: October 26, 2007

Respectfully submitted,

By: /s/ Brian P. Kavanaugh
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CERTIFICATE OF SERVICE

I, Brian P. Kavanaugh, hereby certify that on October 26, 2007, I caused a true and correct copy of the foregoing, ANSWER AND AFFIRMATIVE DEFENSES OF BOEHRINGER INGELHEIM Roxane, INC. TO REVISED FIRST AMENDED CONSOLIDATED COMPLAINT, to be served on all counsel of record in accordance with the Court's Case Management Order No. 2.

Dated: October 26, 2007

/s/ Brian P. Kavanaugh